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10/542,916	07/20/2005	Patrick Colin Hickey	RGC-LUX-P1	9549	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/542.916 HICKEY, PATRICK COLIN Office Action Summary Examiner Art Unit Shun Lee 2884 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 July 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-3.5-7.11-19.21 and 22 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-3,5-7,11-19,21 and 22 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 20 July 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1,121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other:

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### DETAILED ACTION

### Claim Objections

- 1. Claims 1 and 19 are objected to because of the following informalities:
  - (a) in claim 1, "plat" on line 5 should probably be --plate--; and
- (b) in claim 19, "molecules" on line 2 should probably be --comprises molecules--.
  Appropriate correction is required.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16, 17, 21, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant cites (last three paragraphs on pg. 11 of remarks filed 2 July 2008) original claim 15 and page 5, lines 11-23 as support for amended claim 16. Original claim 15 recites "A kit according to either one of Claims 12 and 13, comprising three or more devices, each having a light output of a distinct intensity to the other devices of said kit" and the specification discloses (pg. 5, lines 11-18) that "As the luminescent device of the present invention is small enough to be housed in a single well of a sample holder of a luminometer or other scientific apparatus measuring optical output, it is possible for the luminescent device to be left in the apparatus during use.

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even when other wells contain test materials". Therefore, there does not appear to be a written description of the claim limitations "means for obtaining a reading of light output from the luminescent device" and "means for adjusting the reading of light output of the apparatus to the predetermined intensity of the light output of the luminescent device" in the application as filed.

Further, applicant has not pointed out where new dependent claim 21 is supported, nor does there appear to be a written description of the claim limitation "the standard size well plate is ... a 6, 12, 24, 36, 48 ... well plate" in the application as filed.

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 16, 17, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim elements "means for obtaining a reading of light output from the luminescent device" and "means for adjusting the reading of light output of the apparatus to the pre-determined intensity of the light output of the luminescent device" are means (or step) plus function limitations that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function.

The recitation is unclear and imprecise because although the specification disclosed steps of obtaining a reading of light output from the luminescent device and adjusting the reading of light output of the apparatus to the pre-determined intensity of the light output of the luminescent device (in lines 6-8 on pg. 10 of the specification as filed), the specification does not disclose any structure for carrying out the steps of

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obtaining a reading of light output from the luminescent device and adjusting the reading of light output of the apparatus to the pre-determined intensity of the light output of the luminescent device. Therefore one of ordinary skill in the art does not know what structural limitations are required for the apparatus "selected from the group consisting of a luminometer, a fluorometer, a spectrophotometer, a scintillation counter, a photomultiplier, an avalanche photodiode or a CCD camera", thereby rendering the claims indefinite.

Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112. sixth paragraph; or
- (b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

- (a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification,

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perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP 2181 and 608.01(o).

#### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1, 3, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. (DE 38 16 489 A1) in view of Nast (US 4.575.143).

In regard to claims 1 and 21, it should be noted that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" (*Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)) if the prior art apparatus teaches all the structural limitations of the claim (MPEP § 2114). Thus, "for use in a light measuring apparatus" and "the apparatus selected from the group consisting of a luminometer, a fluorometer, a spectrophotometer, a scintillation counter, a photomultiplier, an avalanche photodiode or a CCD camera" were not given any patentable weight since the light measuring apparatus does not appear to impose any additional structural limitations on the claimed luminescent device. Kessler *et al.* disclose (Figs. 1 and 2) a luminescent device comprising a gaseous tritium light source (GTLS 100) within a housing (101), the housing (101) being within an outer casing (9b), the luminescent device providing a light output of pre-determinable intensity (see EPO automated translation of abstract), wherein the device is sized and shaped (e.g., a 3 mm diameter

cylinder with a height of 15 mm; see EPO automated translation of column 2, lines 60-61) to be removably inserted in an individual well of a standard size well plate (e.g., a BD Falcon™ 6 well flat bottom plate has for each individual well a 9.6 cm² growth area and 15.5 ml well volume or ~35 mm well diameter and ~16 mm depth). The luminescent device of Kessler et al. lacks that the outer casing is magnetic. Nast teaches (column 1, lines 51-52) to provide a magnetic handling tool in order to retrieve small objects having a magnetic component from locations that cannot be reached by a mechanical tool. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a magnetic outer casing for the luminescent device of Kessler et al., in order to retrieve the luminescent device from locations that cannot be reached by hand.

In regard to claim 3 which is dependent on claim 1, Kessler *et al.* also disclose (Fig. 2) an outer casing (9b) that inherently has at least one optically transparent or translucent portion to allow for the transmission of light from the GTLS (100).

 Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of Nast as applied to claim 1 above, and further in view of MacHutchin et al. (US 2,953,684).

In regard to claim **2** which is dependent on claim 1, the modified device of Kessler *et al.* lacks an explicit description that the GTLS comprises 10 to 20 mCi of tritium. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, lines 3-11) that in one embodiment the GTLS have a radiant flux of approximately 15 µlm to 3.5 mlm and that the radiant flux can be adjusted by the tritium gas pressure

for a given luminescent device configuration. Since Kessler *et al.* do not disclose and/or require a specific tritium gas pressure, one having ordinary skill in the art at the time of the invention would reasonably interpret the unspecified tritium gas pressure of Kessler *et al.* as a result effective variable that is to be adjusted so as to obtain a desired radiant flux. Further, MacHutchin *et al.* teach (column 3, line 65 to column 4, line 36) that for a given luminescent device configuration, the number of curies of gas depends on the gas pressure. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the tritium gas pressure (*e.g.*, 10 to 20 mCi of tritium gas) in the modified device of Kessler *et al.*, in order to obtain a desired radiant flux from the luminescent device.

 Claims 5, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of Nast as applied to claims 1 and 3 above, and further in view of Adams et al. (US 6,549,279).

In regard to claim 5 which is dependent on claim 3, the modified device of Kessler et al. lacks an explicit description that the transparent or translucent portion comprises a neutral density filter. However, Kessler et al. also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams et al. teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a neutral

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density filter as the transparent or translucent portion in the modified device of Kessler et al., in order to obtain a second calibration radiant flux from the same luminescent device.

In regard to claim **7** which is dependent on claim 1, the claim limitation "colouring means" is being treated under 35 U.S.C. 112, sixth paragraph and has been construed to cover the corresponding structure described in the specification (*e.g.*, "Coloured filters" in lines 29-31 on pg. 14) and equivalents thereof (MPEP § 2181). The modified device of Kessler *et al.* lacks an explicit description that the device further comprises coloring means to alter the color of the light output of the GTLS. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes for several pre-selected wavelengths. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a filter in the modified device of Kessler *et al.*, in order to obtain light having a desired wavelength.

In regard to claim 12 which is dependent on claim 1, the modified device of Kessler et al. lacks an explicit description that said device comprises a filter array. However, Kessler et al. also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the

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GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a filter array for the modified device of Kessler *et al.*, in order to obtain a plurality of different calibration radiant fluxes from the same luminescent device.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over
 Kessler et al. in view of Nast as applied to claim 3 above, and further in view of
 Adams et al. (US 6,549,279) and Terashita et al. (US 5,073,008).

In regard to claim **6** which is dependent on claim 3, the modified device of Kessler *et al.* lacks an explicit description that the transparent or translucent portion is formed from glass or plastic. However, Kessler *et al.* also disclose (see EPO automated translation of column 3, line 63 to column 4, line 12) that in one embodiment the GTLS (100 in Fig. 2) can be arranged before the interference filter disc (8 in Fig. 2), to change the wavelength of the GTLS (100 in Fig. 2). Further, Adams *et al.* teach (column 8, lines 44-66) to provide a plurality of neutral density filters, in order to obtain a plurality of different calibration radiant fluxes. In addition, Terashita *et al.* teach (column 6, lines 65-68) that a neutral density filter comprises a glass plate or a plastic plate. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a neutral density filter formed from glass or plastic as the transparent or translucent portion in the modified device of Kessler *et al.*, in order to obtain a second calibration radiant flux from the same luminescent device.

 Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of Nast as applied to claim 1 above, and further in view of Gelman et al. (US 5,389,774).

In regard to claim 11 which is dependent on claim 1, the modified device of Kessler et al. lacks that said device comprises a scalebar graticule. However, Gelman et al. teach (Fig. 4) to provide a calibration device comprising a light source (16) and scalebar graticule (15), in order to calibrate an optical measuring system. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a scalebar graticule in the modified device of Kessler et al., in order to calibrate an optical measuring system.

 Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of Nast as applied to claim 1 above, and further in view of Leveille (US 2002/0096667).

In regard to claims 13 and 15 which are dependent on claim 1, Kessler et al. lacks a kit further comprising an additional one or more luminescent devices, wherein each of said devices providing a light output of a distinct intensity to the other devices of said kit. However, Leveille teaches (paragraphs 1-9) to provide a calibration light kit, in order to calibrate a light measuring apparatus. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a plurality of the luminescent devices of Kessler et al. having different intensities as a calibration kit.

In regard to claim 14 which is dependent on claim 13, the kit of Kessler et al. lacks a magnetic handling tool. Nast teaches (column 1, lines 51-52) to provide a

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magnetic handling tool in order to retrieve small objects having a magnetic component from locations that cannot be reached by a mechanical tool. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a magnetic handling tool for the kit of Kessler et al., in order to retrieve the luminescent devices from locations that cannot be reached by hand.

 Claims 16-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. (DE 38 16 489 A1) in view of Nast (US 4,575,143) and Valenta (US 5,321,261).

In regard to claims **16**, **17**, and **22** in so far as understood, the cited prior art is applied as in claim 1 above. Kessler *et al.* also disclose (see EPO automated translation of column 3, line 35 to column 4, line 25) a method for calibrating an apparatus comprising the steps of: obtaining a reading of light output from the luminescent device; and adjusting the reading of light output of the apparatus to the predetermined intensity of the light output of the luminescent device. Kessler *et al.* lacks that the luminescent device is removably inserted into an individual well of a standard size well plate housed in a sample holder of a luminometer, wherein the luminescent device is left in the luminometer during use so that the calibration of the machine may be tested whilst measuring the analyte sample. However, Valenta teaches a luminometer used to measure bioluminescent emissions (column 1, lines 18-19) simultaneously from different wells (column 2, line 67 to column 3, line 2), wherein each of a plurality of radioluminescent standards are placed into individual well (e.g., \$6, \$18, \$30, \$42; column 4, lines 24-26) of a 96 well plate containing a matrix of sample wells

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S1-S96 (column 2, lines 58-62) for calibrating the photomultipliers (e.g., P1-6 and P7-12; column 2, lines 58-62) that can be used for simultaneous measurements from different wells. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to place the luminescent device of Kessler et al. in an individual well of a standard size well plate (e.g., a 6 well plate containing samples in the other individual wells) housed in a sample holder of a luminometer, in order to measure absolute luminescence from the samples.

In regard to claims **18** and **19** which are dependent on claim 1, the cited prior art is applied as in claims 16, 17, and 22 above. Kessler *et al.* disclose (see EPO automated translation of column 3, line 35 to column 4, line 25) a method of analyzing a sample, said method comprising:

- (a) measuring the intensity of light emitted by the luminescent device;
- (b) adjusting the reading of light output of the apparatus to the pre-determined intensity of the light output of the luminescent device; and
- (c) obtaining a reading of light output from the sample.

The method of Kessler et al. lacks that the luminescent device placed and left in an individual well (of a standard size well plate placed in a sample holder of the apparatus) during use so that the calibration of the machine may be tested whilst measuring an analyte sample comprising molecules or living cells placed in another well of the standard size well plate. However, Valenta teaches a luminometer used to measure bioluminescent emissions (column 1, lines 18-19) simultaneously from different wells (column 2, line 67 to column 3, line 2), wherein each of a plurality of radioluminescent

standards are placed into individual well (e.g., S6, S18, S30, S42; column 4, lines 24-26) of a 96 well plate containing a matrix of sample wells S1-S96 (column 2, lines 58-62) for calibrating the photomultipliers (e.g., P1-6 and P7-12; column 2, lines 58-62) that can be used for simultaneous measurements from different wells. Further, bioluminescence is defined <sup>1</sup> as "the emission of light from living organisms; also: the light so produced". Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use the luminescent devices of Kessler et al. to measure absolute bioluminescence from living cells by placing luminescent devices into individual wells (e.g., S6, S18, S30, S42) and samples of living cells into other individual wells (e.g., S8, S20, S32, S44) of a 96 well plate.

## Response to Arguments

 Applicant's arguments filed 2 July 2008 have been fully considered but they are not persuasive.

Applicant argues that there is no indication or suggestion that the device disclosed in Kessler *et al.* is shaped or sized to fit inside a well of most standard size well plates and Kessler *et al.* teaches away from the claimed device since the 3 mm by 15 mm device of Kessler *et al.* would be too large to fit inside a well of most standard size well plates. Examiner respectfully disagrees. First, it should be noted that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim (MPEP § 2114). In this case,

<sup>&</sup>lt;sup>1</sup> Merriam Webster's Collegiate Dictionary 10<sup>th</sup> Edition

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Kessler *et al.* disclose (see EPO automated translation of column 2, lines 60-61) an embodiment wherein the GTLS is a 3 mm diameter cylinder with a height of 15 mm. Thus the exemplary GTLS of Kessler *et al.* is of a size and shape to be housed in sample holder (*e.g.*, a commercially available 6-well plate) having optically clear walls for various standard assays with a light measuring apparatus. Therefore, applicant's arguments are not persuasive.

In response to applicant's argument that sample measurement occurs after calibration and that no absolute measurement is taken by Valenta, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

#### Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Shun Lee whose telephone number is (571) 272-2439.

The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, David Porta can be reached on (571) 272-2444. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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/S. L./

Examiner, Art Unit 2884

/David P. Porta/

Supervisory Patent Examiner, Art Unit 2884